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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/763,628

01/23/2004

Carter R. Anderson

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EXAMINER

SAMALA, JAGADISHWAR RAO

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

12/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/763,628	Applicant(s) ANDERSON ET AL.	
	Examiner Jagadishwar R. Samala	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/12/2007 has been entered.

Response to Arguments

2. Applicant's arguments filed on 10/12/2007 with respect to the rejection(s) of claims 1-24 under 103(a) have been fully considered but they are not persuasive. However, upon further consideration, a new ground(s) of rejection is made in view of changes made in to the scope of the claims.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 10-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is vague and indefinite because it is unclear what is meant by "a disposable container separate from any skin-worm patch device," because said term is not defined in the specification. An ordinary skilled artisan would not be apprised of the meets and bounds of the term "a disposable container separate from any skin-worm patch device" and would not be able to ascertain its meaning based on applicant's disclosure.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 10-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marcenyac et al. (US 2004/0146547 A1).

With respect to claims 10-24, Marcenyac et al. discloses an article (a transdermal patch) includes a reservoir housing a dye and/or medicament inactivating agent in

communication with the reservoir that is released when the reservoir is opened or revealed (see 0009). And further, the article may include a pocket having a sealable opening and formed between first and second portions of the opposite side of the inner layer, wherein the opening is optionally sealed by a flap covered at least in part by a permanent pressure and/or heat sensitive adhesive (see 0014). And also the disposing of a transdermal patch includes placing a transdermal patch within the article, sealing the patch within a pocket of the article, such that the article releases the detection material and/or inactivating agent when the reservoir is opened and thus the article prevents or hinders misuse of the active agent contained in the transdermal dosage form (see 0022). And further, article includes a medicament layer having a transfer side and an opposite side; a first adhesive contained in the medicament layer; an outer layer having a medicament layer facing side and an opposite side, the medicament layer being joined to outer layer to form one or more closed material reservoir; and a detection material and/or medicament-inactivator in the reservoir which is released when the reservoir is opened (see 0023-0027). And also, discloses a method of disposing of a transdermal patch comprising: placing said transdermal patch on said opposite side of said inner layer of an article and contacting said adhesive covering at least a portion of said opposite side of said inner layer with a different portion of said opposite side of said inner layer to form a sealed pocket enclosing said transdermal patch (see 0044 and 0045). And medicament layer contains an opiate e.g. fentanyl; the inactivating agent include the rat or human mu-opioid receptor; opioid-neutralising antibodies; narcotic antagonists such as naloxone, naltrexone and nalmedrone; dysphoric

or irritating agents such as scopolamine, ketoamine, artropine or mustard oils or any combinations thereof (see 0112 and 0114). And in practice, if the active agent in a trasderaml patch to be disposed of by placing it in the present article were an opioid, the inactivating agent renders the active agent unavailable through inactivation, such as for example chemical inactivation or alteration of the receptor binding site of the active agent; biounavailability; physical unavailability; loss of appeal of the active agent to the abuser, such as for example, an inactivating agent which creates an intolerably bad taste or an intolerable reaction such as extreme nausea or the like; or something similar thereto. One or more inactivating agent(s) may be used (see 0099). And further discloses that it is known in prior art (US 5,804,215) to Cubbage et al. relates to disposal system for a transdermal patch comprising a pouch for transport of the patch and disposal system encapsulates a trasndermal patch and prevents access to it.

Marcenyac et al. meets all the limitations of instant claims except that it uses different anti-abuse substance. However, Marcenyac et al. teaches use of various anti-abuse substances directly related to effective in preventing abuse, particularly if the active agent is a narcotic or a controlled substance (e.g. used dosage forms containing excess or unused opioids which may be tampered with by chewing or extraction by a drug abuser). Since the inactivating agents is directly related to anti-abuse substance, and the prior art teaches the same subject matter (disposable of transdermal patch containing residual or unused opioid in a separate pouch) by similar process, it is examiner's position that, in the absence of evidence to the contrary, a suitable specific anti-abuse substance is also either anticipated by Marcenyac, or obviously provided by

practicing the invention of prior art. It should be noted that where claimed and prior art products are shown to be identical or substantially identical in composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. See MPEP § 2112.01.

Conclusion

1. No claims are allowed at this time.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jagadishwar R Samala
Examiner
Art Unit 1618

Zohreh Fay
Primary Examiner
Art Unit 1618

